K083851
1 of 3

510(k) Summary
(As required by 21 CFR 807.92(a))

MAY 15 2009

A. Submitter Information

Inviro Medical
1755 North Brown Road
Suite 150
Lawrenceville, GA 30043

Phone Number: 678-405-4031
Fax Number: 678-405-4044
Contact: Jim Barley
Director RA/QA

Trade Name: InviroBlunt/InviroBlunt w/EZ Wings Cannula

B. Device Information

Trade/Proprietary Name:	InviroBlunt and /InviroBlunt w/EZ Wings Cannula
Common name of device:	Syringe Cannula
Classification Name:	Set, I.V. Fluid Transfer
Product Code:	80 LHI
Regulatory Class:	II
Classification Number:	880.5440
Reason for 510(k):	New Device

C. Predicate Device: Inviro Medical InviroLink and InviroLink w/EZ Wings Cannula

Predicate 510(k) #: K071307

Predicate product code: LHI

D. Device Description

The InviroBlunt/InviroBlunt Cannula were designed to replace hypodermic needles currently for withdrawal of medication from rubber-stoppered vials or injection into I.V. Systems and pre-slit septums covering injection sites.

The family of InviroBlunt Plastic Cannulas are 18 gauge stainless steel blunt cannulas for penetrating medicine vials and dispensing medications or for injection into I.V. Systems and for use in pre-slit septums covering injection sites. Following is a list of the InviroBlunt Cannulas:

1. InviroBlunt, Model # 120022
2. InviroBlunt with EZ wings, Model # 120522

The InviroBlunt Cannulas are used in conjunction with a syringe to penetrate rubber-stopered medicine vials and pre-slit septums covering injection sites. The cannula is pre-lubricated to reduce septum insertion forces. The devices are individually packaged and are provided sterile and are labeled as single use.

E. Statement of Indications for Use

The InviroBlunt and InviroBlunt w/EZ Wings Cannulas are used in conjunction with a syringe as an additive device for aspiration from multi-dose medicine vials or injection into I.V. Systems and pre-slit septums covering injection sites.

F. Comparison of Required Technological Characteristics:

Information was submitted to demonstrate that there are no significant differences in technological characteristics between the InviroBlunt and InviroBlunt w/EZ Wings Cannulas and the cited predicate device.

G. Summary and Conclusion of Nonclinical and Clinical Tests:

The InviroBlunt/InviroBlunt w/EZ Wings Cannulas met the following product/performance requirements:

A visual inspection of the device showed that the surface of the device was smooth and without oil contamination or extraneous matter or other defects. The lubricant on the cannula was invisible and the device was free of flash and burrs.

The color of each hub and cap met the product requirement.

Dimensional – All components of the InviroBlunt and InviroBlunt w/EZ Wings met the dimensional, visual and functional requirements listed on the part/assembly drawing.

Functional – The InviroBlunt and InviroBlunt w/EZ Wings met the requirements for Cap Pull off Force, InviroBlunt/Syringe interface, penetration, bending and tip breaking Forces and flow rate.

Interface – The interfaces between the InviroBlunt and the medicine vial stopper and the InviroBlunt and the syringe luer lock fitting were secure and able to withstand 330 kPa of pressure for 30 seconds without leakage.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2009

Mr. James Barley
Director of Regulation Affairs/Quality Assurance
Inviro Medical Devices, Incorporated
1755 North Brown Road, Suite 150
Lawrenceville, Georgia 30043

Re: K083851
Trade/Device Name: InviroBlunt and /InviroBlunt w/EZ Wings Cannula
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: March 31, 2009
Received: April 22, 2009

Dear Mr. Barley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K083851

Device Name:

Indications For Use:

The InviroBlunt and InviroBlunt w/EZ Wings Cannulas are used in conjunction with a syringe as an additive device for aspiration from multi-dose medicine vials or injection into I.V. Systems and pre-slit septums covering injection sites.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for L.C.O.R. Colburn 05/15/09
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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